

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT PTO-1449</b>	<b>ATTY. DOCKET NO.</b> 1662/61902	<b>SERIAL NO.</b> 10/699,991
	<b>APPLICANT</b> E. Itzhak LERNER et al.	
	<b>FILING DATE</b> November 3, 2003	<b>GROUP</b> 1617

**U. S. PATENT DOCUMENTS**










EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE

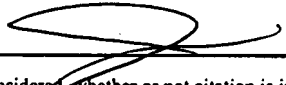
**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
✓	WO 01/037808	November 22, 2000	WO				
✓	WO 01/028555	October 18, 2000	WO				

**OTHER DOCUMENTS**

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
✓	<i>Physicians Desk Reference 55th ed. 670-673 (Medical Economics Co.: Montvale, N.J.2001).</i>
✓	Abbruzzese, G., "The Medical Management of Spasticity" <i>Eur. J. Neurol.</i> , 2002, Suppl. 1,30-34, and 53-61.
✓	Kita, M. and Goodkin, D. E., "Drugs Used to Treat Spasticity" <i>Drugs</i> , 2000, 59(3), 48795.
✓	Groves, L., et. al., " Tizanidine Treatment of Spasticity: A Meta Analysis of Controlled, Double-blind, Comparative Studies with Baclofen and Diazepam" <i>Adv. Ther.</i> , 1998, 15(4), 241-51.
✓	Milanov, I., and Georgiev, D., "Mechanisms of Tizanidine Action on Spasticity" <i>Acta. Neurol. Scand.</i> , 1994, 89(4), 274-79).
✓	Schapiro, R. T., "Management of Spasticity, Pain, And Paroxysmal Phenomena in Multiple Sclerosis" <i>Curr. Neurosci. Rep.</i> , 2001, 1(3), 299- 302.
✓	Nance, P. W. , et. al. "Relationship of The Antispasticity Effect of Tizanidine to Plasma Concentration in Patients with Multiple Sclerosis" <i>Arch. Neurol.</i> , 1997, 54(6), 731-36.
✓	Smith, C., et. al., "Tizanidine Treatment of Spasticity Caused by Multiple Sclerosis: Results of a Double-blind, Placebo Controlled Trial. US Tizanidine Study Group" <i>Neurology</i> , 1994, 44(11 Suppl. 9), S34-43).
✓	Nance, P. W. et. al., "Efficacy And Safety of Tizanidine in The Treatment of Spasticity in Patients with Spinal Cord Injury. North American Tizanidine Study Group" <i>Neurology</i> , 1994, 44(11 suppl. 9), S44 -52.

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
		Burchiel, K. J. and Hsu, F. P., "Pain And Spasticity after Spinal Cord Injury: Mechanisms And Treatment" <i>Spine</i> , 2001, 26(24 suppl.), S 146-60).
		Gelber, D. A. et. al., "Open-label Dose- titration Safety and Efficacy Study of Tizanidine Hydrochloride in The Treatment of Spasticity Associated with Chronic Stroke" <i>Stroke</i> , 2001, 32(8) 1841-6.
		Meythaler, J. M. et. al., "Prospective Assessment of Tizanidine for Spasticity Due to Acquired Brain Injury" <i>Arch. Phys. Med. Rehabil.</i> , 2001, 82(9), 1159-63).
		Smith, T. R. , "Low-dose Tizanidine with Nonsteroidal Anti-inflammatory Drugs for Detoxification from Analgesic Rebound Headache, <i>Headache</i> , 2002, 42(3), 175-7.
		Saper, J. R. , et. al. , "An Open-label Dose-titration Study of The Efficacy And Tolerability of Tizanidine Hydrochloride Tablets in The Prophylaxis of Chronic Daily Headache, <i>Headache</i> , 2001, 41(4), 357-68.
		Murros, K., et. al., "Modified Release Formulation of Tizanidine in Chronic Tension-type Headache", <i>Headache</i> , 2000, 40(8), 633-7.
		D'Alessandro, R. , "Tizanidine for Chronic Cluster Headache" <i>Arch. Neurol.</i> , 1996, 53(11) 1093.
		Roberts, R. C. "Pharmacokinetics and Pharmacodynamics of Tizanidine" <i>Neurology</i> 1994, 44 (11 suppl 9), S29-31.
		de- Graff, E. M., et. al., "A Case of Tizanidine-induced Hepatic Injury, <i>J Hepatol.</i> , 1996, 25(5), 772-3.

EXAMINER		DATE CONSIDERED 6/25/07
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

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	<b>FILING DATE</b> November 3, 2003	<b>GROUP</b> <del>1614</del> 1617

**U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE
<i>[initials]</i>	5,576,014	Nov. 19, 1996	Mizumoto et al.	<i>[initials]</i>		

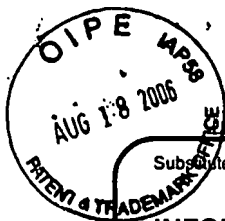
**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
<i>[initials]</i>	2,197,198 A	May 18, 1988	Gt. Britain	<i>[initials]</i>			
<i>[initials]</i>	WO 03/075893 A1	Sept. 18, 2003	PCT	<i>[initials]</i>			

**OTHER DOCUMENTS**

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.

<b>EXAMINER</b> <i>[signature]</i>	<b>DATE CONSIDERED</b> 6/25/07
<small>EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>	



Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

### Complete if Known

Application Number	10/699,991
Filing Date	November 3, 2003
First Named Inventor	E. Itzhak LERNER et al.
Art Unit	1614 1617
Examiner Name	Not Yet Assigned
Attorney Docket Number	1662/61902

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
✓		6,255,502	Jul 3, 2001	Lawrence John Penkler et al.	
		6,248,363	Jun 19, 2001	Mahesh V. Patel et al.	
		5,466,464	Nov 14, 1995	Katsuhiko Masaki et al.	
		2003/0206954	Nov 6, 2003	E. Itzhak Lerner et al.	
		5,702,717	Dec 30, 1997	Younsik Cha et al.	
		6,201,072	Mar 13, 2001	Ramesh C. Rathi et al.	
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		3,632,743	Jan 4, 1972	Leo Geller et al.	
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		3,972,995	Aug 3, 1976	Andrew G. Tsuk et al.	
		4,229,447	Oct 21, 1980	William R. Porter	
		4,020,558	May 3, 1977	René Courmut et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
✓		WO 03/057136 A2	Jul 17, 2003	Teva Pharmaceutical Industries Ltd.		
✓		WO 03/057136 A3	Jul 17, 2003	Teva Pharmaceutical Industries Ltd.		
✓		WO 99/04764	Feb 4, 1999	Perlo Products Ltd.		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
✓		Remington's Pharmaceutical Sciences 16 <sup>th</sup> ed., page 670, (Mack Publishing: Easton, Pa. 1980).	

Examiner Signature

Date Considered

6/25/07

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